

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Bernd RIEDL



Serial No.: 09/993,647

Group Art Unit: 1624

Filed: November 27, 2001

Examiner: Deepak R. RAO

For:  $\omega$ -CARBOXYARYL SUBSTITUTED DIPHENYL UREAS AS RAF KINASE  
INHIBITORS

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98**

Commissioner for Patents  
P.O. Box 1450  
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Sir:

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  - within three months of the actual filing date of the national phase of a PCT application; OR
  - before the mailing of a first substantive office action (including after filing of an RCE).
  
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  - a final rejection under 37 C.F.R. 1.113;
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  - a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

- the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
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- Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
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Cited Materials

- Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. \_\_\_\_\_, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- Copies of materials listed but not attached are on the attached diskette.
- Copies of the materials listed are attached.

Non-English Language References

An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).

A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

X = document of particular relevance when it is taken alone

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A = document defining the general state of the art

O = non-written disclosure

P = intercalated document

T = document cited to understand the theory or principle underlying the invention

E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date

D = cited in the application

L = cited for another reason

& = publication of member of same patent family

Translation of other relevant information on foreign search report

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Other Information


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Respectfully submitted,

  
Richard J. Traverso, Reg. No. 30,595  
Attorney for Applicants

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*for RJT*

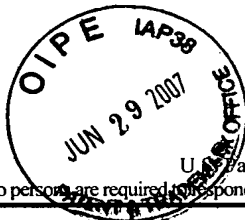
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Attorney Docket No.: BAYER-0018-A

Date: June 29, 2007

RJT:jmj

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 2

Complete if Known

Application Number	09/993,647
Filing Date	November 27, 2001
First Named Inventor	Bernd Riedl et al.
Group Art Unit	1624
Examiner Name	Deepak R. Rao
Attorney Docket Number	BAYER-0018A

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
	1	<u>Richly H, Henning BF, Kupsch P, Passarge K, Grubert M, Hilger RA, Christensen O, Brendel E, Schwartz B, Ludwig M, Flashar C, Voigtmann R, Scheulen ME, Seeber S, Strumberg D.</u> Results of a Phase I trial of sorafenib (BAY 43-9006) in combination with doxorubicin in patients with refractory solid tumors. <u>+Ann Oncol.</u> 2006 May;17(5):866-73. Epub 2006 Feb 24.	
	2	<u>Moore M, Hirte HW, Siu L, Oza A, Hotte SJ, Petrenciuc O, Cihon F, Lathia C, Schwartz B.</u> Phase I study to determine the safety and pharmacokinetics of the novel Raf kinase and VEGFR inhibitor BAY 43-9006, administered for 28 days on/7 days off in patients with advanced, refractory solid tumors. <u>Ann Oncol.</u> 2005 Oct;16(10):1688-94. Epub 2005 Jul 8	
	3	<u>Eisen T, Ahmad T, Flaherty KT, Gore M, Kaye S, Marais R, Gibbens I, Hackett S, James M, Schuchter LM, Nathanson KL, Xia C, Simantov R, Schwartz B, Poulin-Costello M, O'Dwyer PJ, Ratain MJ.</u> Sorafenib in advanced melanoma: a Phase II randomised discontinuation trial analysis. <u>Br J Cancer.</u> 2006 Sep 4;95(5):581-6. Epub 2006 Aug 1.	
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	5	<u>Jain L, Venitz J, Figg WD.</u> Randomized discontinuation trial of sorafenib (BAY 43-9006). <u>Cancer Biol Ther.</u> 2006 Oct;5(10):1270-2. Epub 2006 Oct 16.	
	6	<u>Siu LL, Awada A, Takimoto CH, Piccart M, Schwartz B, Giannaris T, Lathia C, Petrenciuc O, Moore MJ.</u> Phase I trial of sorafenib and gemcitabine in advanced solid tumors with an expanded cohort in advanced pancreatic cancer. <u>Clin Cancer Res.</u> 2006 Jan 1;12(1):144-51.	
	7	<u>Clark JW, Eder JP, Ryan D, Lathia C, Lenz HJ.</u> Safety and pharmacokinetics of the dual action Raf kinase and vascular endothelial growth factor receptor inhibitor, BAY 43-9006, in patients with advanced, refractory solid tumors. <u>Clin Cancer Res.</u> 2005 Aug 1;11(15):5472-80.	
	8	<u>Ahmad T, Eisen T.</u> Kinase inhibition with BAY 43-9006 in renal cell carcinoma. <u>Clin Cancer Res.</u> 2004 Sep 15;10(18 Pt 2):6388S-92S.	
	9	<u>Kupsch P, Henning BF, Passarge K, Richly H, Wiesemann K, Hilger RA, Scheulen ME, Christensen O, Brendel E, Schwartz B, Hofstra E, Voigtmann R, Seeber S, Strumberg D.</u> Results of a phase I trial of sorafenib (BAY 43-9006) in combination with oxaliplatin in patients with refractory solid tumors, including colorectal cancer. <u>Clin Colorectal Cancer.</u> 2005 Sep;5(3): abstract.	
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	11	<u>Mross K, Steinbild S, Baas F, Gmehling D, Radtke M, Voliotis D, Brendel E, Christensen O, Unger C.</u> Results from an in vitro and a clinical/pharmacological phase I study with the combination irinotecan and sorafenib. <u>Eur J Cancer.</u> 2007 Jan;43(1):55-63. Epub 2006 Nov 13.	
	12	<u>Richly H, Kupsch P, Passage K, Grubert M, Hilger RA, Voigtmann R, Schwartz B, Brendel E, Christensen O, Haase CG, Strumberg D.</u> Results of a phase I trial of BAY 43-9006 in combination with doxorubicin in patients with primary hepatic cancer. <u>Int J Clin Pharmacol Ther.</u> 2004 Nov;42(11):650-1. No abstract available.	
	13	<u>Hilger RA, Kredtke S, Scheulen ME, Seeber S, Strumberg D.</u> Correlation of ERK-phosphorylation and toxicities in patients treated with the Raf kinase inhibitor BAY 43-9006. <u>Int J Clin Pharmacol Ther.</u> 2004 Nov;42(11):648-9. No abstract available.	
	14	<u>Richly H, Kupsch P, Passage K, Grubert M, Hilger RA, Kredtke S, Voliotis D, Scheulen ME, Seeber S, Strumberg D.</u> A phase I clinical and pharmacokinetic study of the Raf kinase inhibitor (RKI) BAY 43-9006 administered in combination with doxorubicin in patients with solid tumors. <u>Int J Clin Pharmacol Ther.</u> 2003 Dec;41(12):620-1. No abstract available.	

15	<u>Mross K, Steinbild S, Baas F, Reil M, Buss P, Mersmann S, Voliotis D, Schwartz B, Brendel E. Drug-drug interaction pharmacokinetic study with the Raf kinase inhibitor (RKI) BAY 43-9006 administered in combination with irinotecan (CPT-11) in patients with solid tumors. Int J Clin Pharmacol Ther. 2003 Dec;41(12):618-9. No abstract available.</u>
16	<u>Hilger RA, Diaz-Carballo D, Bauer S, Kredtke S, Scheulen ME, Seeber S, Strumberg D. Circadian rhythm in the regulation of the MAP kinase pathway--pitfall in the determination of surrogate parameters? Int J Clin Pharmacol Ther. 2003 Dec;41(12):614-5. No abstract available.</u>
17	<u>Strumberg D, Voliotis D, Moeller JG, Hilger RA, Richly H, Kredtke S, Beling C, Scheulen ME, Seeber S. Results of phase I pharmacokinetic and pharmacodynamic studies of the Raf kinase inhibitor BAY 43-9006 in patients with solid tumors. Int J Clin Pharmacol Ther. 2002 Dec;40(12):580-1. No abstract available.</u>
18	<u>Hilger RA, Kredtke S, Hedley D, Moeller JG, Bauer RJ, Stellberg W, Seeber S, Scheulen ME, Strumberg D. ERK1/2 phosphorylation: a biomarker analysis within a phase I study with the new Raf kinase inhibitor BAY43-9006. Int J Clin Pharmacol Ther. 2002 Dec;40(12):567-8. No abstract available.</u>
19	<u>Abou-Alfa GK, Schwartz L, Ricci S, Amadori D, Santoro A, Figer A, De Greve J, Douillard JY, Lathia C, Schwartz B, Taylor I, Moscovici M, Saltz LB. Phase II study of sorafenib in patients with advanced hepatocellular carcinoma. J Clin Oncol. 2006 Sep 10;24(26):4293-300. Epub 2006 Aug 14.</u>
20	<u>Ratain MJ, Eisen T, Stadler WM, Flaherty KT, Kaye SB, Rosner GL, Gore M, Desai AA, Patnaik A, Xiong HQ, Rowinsky E, Abbruzzese JL, Xia C, Simantov R, Schwartz B, O'Dwyer PJ. Phase II placebo-controlled randomized discontinuation trial of sorafenib in patients with metastatic renal cell carcinoma. J Clin Oncol. 2006 Jun 1;24(16):2505-12. Epub 2006 Apr 24.</u>
21	<u>Veronese ML, Mosenkis A, Flaherty KT, Gallagher M, Stevenson JP, Townsend RR, O'Dwyer PJ. Mechanisms of hypertension associated with BAY 43-9006. J Clin Oncol. 2006 Mar 20;24(9):1363-9. Epub 2006 Jan 30.</u>
22	<u>Strumberg D, Richly H, Hilger RA, Schleucher N, Korfee S, Tewes M, Faghih M, Brendel E, Voliotis D, Haase CG, Schwartz B, Awada A, Voigtman R, Scheulen ME, Seeber S. Phase I clinical and pharmacokinetic study of the Novel Raf kinase and vascular endothelial growth factor receptor inhibitor BAY 43-9006 in patients with advanced refractory solid tumors. J Clin Oncol. 2005 Feb 10;23(5):965-72. Epub 2004 Dec 21.</u>
23	<u>Hanna N. Second-line treatment of non-small cell lung cancer: big targets, small progress; small targets, big progress? J Thorac Oncol. 2006 Nov;1(9):927-8. No abstract available.</u>
24	<u>Escudier B, Eisen T, Stadler WM, Szczylik C, Oudard S, Siebels M, Negrier S, Chevreau C, Solska E, Desai AA, Rolland F, Demkow T, Hutson TE, Gore M, Freeman S, Schwartz B, Shan M, Simantov R, Bukowski RM, TARGET Study Group. Sorafenib in advanced clear-cell renal-cell carcinoma. N Engl J Med. 2007 Jan 11;356(2):125-34.</u>
25	<u>Gridelli, Cesare; Maione, Paolo; Del Gaizo, Filomena; Sorafenib an Sunitinib in the Treatment of Advanced Non-Small Cell Lung Cancer; Oncologist 2007; 12; 191-200</u>

Examiner Signature		Date Considered	
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